PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

XYREM
(sodium oxybate)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Xyrem is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The request is for continuation of Xyrem (sodium oxybate) AND the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy

OR

- The requested drug is being prescribed for the treatment of cataplexy in narcolepsy in a patient 7 years of age or older AND the diagnosis is confirmed by sleep lab evaluation
  OR
- The requested drug is being prescribed for the treatment of excessive daytime sleepiness in a patient 7 years of age or older with narcolepsy AND the diagnosis is confirmed by sleep lab evaluation
  AND
  - The patient has experienced an inadequate treatment response to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
    OR
  - The patient has experienced an intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
    OR
  - The patient has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate)

  AND
  - If the patient is 18 years of age or older, the patient experienced an inadequate treatment response to armodafinil OR modafinil
    OR
  - If the patient is 18 years of age or older, the patient experienced an intolerance to armodafinil OR modafinil
    OR
  - If the patient is 18 years of age or older, the patient has a contraindication that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil

Quantity Limits Apply.
540 mL/25 days or 1620 mL/75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

REFERENCES

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed October 2019.

3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed October 2019.
4. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and Other Hypersomnias of Central Origin. *Sleep* 2007; 30(12):1705-11.
5. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
6. Krahn, L, Hershner S, et al. Quality Measures for the Care of Patients with Narcolepsy; *Journal of Clinical Sleep Medicine*; 2015; 11(3): 335-55.
7. Nuvigil [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2019.
8. Provigil [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2019.